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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|

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18M1/1118

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EXAMINER

| | |
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| ART. UNIT | PAPER NUMBER |
|-----------|--------------|

58
11/18/97

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

| | | |
|------------------------------|---|---------------------------------------|
| Office Action Summary | Application No. 08/266,154 | Applicant(s) Morrison et al |
| | Examiner Julie E. Reeves, Ph.D. | Group Art Unit 1806 |

Responsive to communication(s) filed on Aug 28, 1997

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 43, 44, 46, 48, 60, 61, 63, 65, 71, 72, 74, 76, and 78-95 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 43, 44, 46, 48, 60, 61, 63, 65, 71, 72, 74, 76, and 78-95 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s) _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. It is noted that applicant has paid for a Notice of Appeal and the brief has been submitted in triplicate on 9/25/96 and that a Notice of Appeal has been filed 6/16/97, when the case did not have an outstanding Final Rejection pending. It is noted that the Office action send 12/11/96 was not made final. Applicant can either request a refund of the appeal fee or can leave the money on account to be applied to the cost of a possible appeal in the future. If a refund is desired, a specific request for a refund must be filed.

2. Claims 78, 82-84, 88-90, 94-95 have been amended. Claims 43-44, 46, 48, 60-61, 63, 65, 71-72, 74, 76, 78-95 are pending. A renumbered, reordered copy of the claims is attached at the back of this Office Action.

Specification

3. The abstract of the disclosure is objected to because it does not described the claimed invention. Correction is required. See MPEP § 608.01(b).

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

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5. The entire first line of the specification needs to be deleted and replaced, in entirety with a new passage reciting all the parent application, their filing date and present status, i.e., now abandoned. This is necessary due to the large number of parent applications, amendments which are not legible. Furthermore, some of the amendments have entered duplicate text.

Claim Rejections - 35 U.S.C. § 112

6. Claims 43-44, 46, 48, 60-61, 63, 65, 71-72, 74, 76, 78-95 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

- a. The claims recite "lymphoid cells" however, the specification does not provide support for lymphoid cells. Applicant is pointed to page 8, lines 32-38 for terminology such as transformed lymphocytes or myelomas that would be sufficient to overcome this rejection.
- b. Claim 82 recites endogenously produced heavy chain being not secreted in a form capable of specifically binding antigen. The specification does not provide adequate support for this concept.
- c. The claims recite antibodies while the specification teaches immunoglobulins. Applicant is invited to point to where the specification provides support for antibodies.

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7. Claims 43-44, 46, 48, 60-61, 63, 65, 71-72, 74, 76, 78-95 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 82, 88, and 94 are indefinite for reciting "but not both" in line four, as it is not clear what this clause refers to. It is suggested that this clause be moved to the end of line 2 for improved clarity.

b. Claims 43-44, 46, 48, 60-61, 63, 65, 71-72, 74, 76, 78-95 are indefinite for reciting "lymphoid" as it is not clear what is meant by this term. As evidenced by Stedman's Medical Dictionary, "lymphoid" is broadly and vaguely defined as "resembling lymph or lymphatic tissue or pertaining to the lymphatic system".

c. Claims 43-44, 46, 48, 60-61, 63, 65, 71-72, 74, 76, 78-95 are indefinite for reciting "antibody" as it is not clear what is meant by this term. Is an antibody a tetramer protein consisting of two heavy chains and two light chains, with variable domains and constant regions and antigen binding regions? How does this differ from an immunoglobulin? Does antibody encompass immunoglobulin fragments?

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d. Claims 81-82 are indefinite for reciting "wherein the cell does not endogenously produce any immunoglobulin chains" because it is not clear how this further limits claim 78. How can a "non-antibody producing cell" produce antibodies?

Previous Rejections

8. The rejection of claims 43-44, 46, 48, 60-61, 63, 65, 71-72, 74, 76, 78-95 under 35 U.S.C. 112, first and second paragraphs, as failing to provide an enabling specification and as being indefinite for reciting "chimeric", "substantially the same as" are withdrawn in view of the amendment to the claims.

9. The rejection of claims 43-44, 46, 48, 60-61, 63, 65, 71-72, 74, 76, 78-95 under 35 U.S.C. 112, first paragraph, as failing to provide an enabling specification has been withdrawn in view of the fact that the claims have been limited to mammalian lymphoid cells.

10. The Declarations of Morrison et al and Shulman et al (Paper no 54, filed 16 Jun 1997) has been considered carefully. The Cox et al reference (Exhibit D) was not published until 15 August 1984, as evidenced by the attached printout. Although that abstract was presented prior to the filing date, the meeting was not held in the United States and therefore, this reference does not meet the criteria of 35 U.S.C. 102 (a or b). The claims are still free of the prior art of record.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie Reeves, Ph.D., whose telephone number is (703) 308-7553. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached on (703) 308-2731. The fax phone number for this Group is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

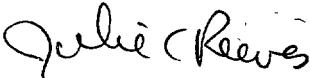
12. Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to **[lila.feisee@uspto.gov]**.

13. All Internet e-mail communications will be made of record in the application file. **PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122.** This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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14. Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Respectfully,



Julie E. Reeves, Ph.D.

(703) 308-7553



LILA FEISEE
SUPERVISORY PATENT EXAMINER
GROUP 1800